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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,790	01/14/2002	Richard A. Rosenbloom	QUIG-1006CIP	3053

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,790	ROSENBLOOM, RICHARD A.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-20 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 9-20, 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/2006 has been entered.

Claim(s) 6, 8, 21-37, 42 have been cancelled. Claim(s) 1-5, 7, 9-20, 38-41 are pending. Claim(s) 1, 4, 39, 41 have been amended. Claim(s) 1-5, 7, 9-20, 38-41 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejections of the last Office Action are maintained for reasons of record and are repeated below for Applicant's convenience. The following new double patenting rejection will now apply also.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-9, and 12-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/288,761 for same reasons of record stated in the Office Action dated October 20, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same method of the treatment comprising the same active agents as the claims of the instant application. Thus, these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 1, 4-9, and 12-20 are seen to be obvious over the claims 1-40 of copending Application No. 10/288,761 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-9, and 12- 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/279,315 for same reasons of record stated in the Office Action dated October 20, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method for the

reduction or treatment of reactive and inflammatory dermatoses comprising the same active agents as the claims of the instant application. One of ordinary skill in the art would recognize that radiation injury in a patient would be reactive and inflammatory dermatoses. Thus, these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 1, 4-9, and 12-20 are seen to be obvious over the claims 1-25 of copending Application No. 10/279,315.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 16-20, 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,753,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method for the reduction or treatment of radiation dermatitis caused by one or more types of ionization radiation by administering a vitamin D compound, antioxidants, hydroxymethyl cellulose, alpha lipoic acid is disclosed.

Response to Arguments

Applicant requests deferral of these provisional obviousness-type double patenting rejections until such time as notice of allowance in said co-pending applications are received is noted. Nonetheless, for the reasons of record, said rejections are maintained at this point.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 7, 9-20, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett (US 6,051,602, PTO-892), and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record).

Kita discloses that vitamin D including vitamin D3 (cholecalciferol), is useful in a dermatological composition for the protection and treatment of the skin and scalp from harmful UV radiation. See 6,162,801, abstract, col. 1, lines 22-24 and 51-67, col. 4, lines 13-16, and col. 8, lines 51 to col. 9.

Bissett (US 6,051,602) discloses that the instant one or more flavonoids (also known as polyphenols and are known to be obtained from green teas extracts, including

catechin, epicatechin, and rutin compounds) are useful in a method of reduction or treatment skin conditions in human resulted from environmental damage or extrinsic factors such as UV radiation, pollution, wind, heat or IR, low humidity, harsh surfactants, by topically applying a composition comprising one or more flavonoids, a pharmaceutically acceptable carrier broadly (e.g., PPG), and other active agents such as anti-inflammatorv aoents and anti-oxidants such as vitamin A (retinol or retinyl derivatives) and C (ascorbic acid), with conventional skin care product additives such as kernel oil, panthenol, to human skin. See in Bissett, the abstract, col. 1, col. 2, lines 14-48, col. 3, lines 13-36 and 53-55, col. 4, lines 13-16, col. 4, lines 65 to col. 5, line 49, col. 6, lines1-55, col. 7, lines 1-10, Example 1 and 3 at col. 9-10, and claims 1-11. Bissett discloses the effective amounts of one or more flavonoid compounds, about 0.01-20%, more preferably, about 0.1-10%, and most preferably about 0.5-5%, within the instant claim (see col. 5, lines 60-64).

Darr et al. discloses that vitamin C such as ascorbic acid or vitamin E is useful in a composition to be administered orally or topically in the treatment of the protection of UV radiation-induced damage. See Summary and page 247.

The prior art does not expressly disclose the employment of the combination of vitamin D3 and ascorbyl palmitate and flavonoid / flavonoid derivatives, and ginseng in a composition to be administered in a method for the treatment or reduction of radiation injury. The prior art does not expressly disclose that the particular radiation is proton, fluoroscopic, alpha, beta, or gamma radiation.

Shimoi et al. discloses that flavonoid / flavonoid derivatives from plant or tea are

antioxidants and have radioprotective effects. See abstract.

Kim et al. discloses that ginseng is known to be useful in the protection of radiation injury. See col. 1, lines 21-27.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the combination of vitamin D3 and ascorbyl palmitate and flavonoid / flavonoid derivatives, and ginseng in a composition to be administered in a method for the treatment or reduction of radiation injury.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of vitamin D3 and ascorbyl palmitate in a composition to be administered in a method for the treatment or reduction of radiation injury since vitamin D such as vitamin D3 is known to be useful for the protection and treatment of the skin and scalp from harmful UV radiation. Antioxidants such as vitamin C (ascorbic acid) is known to be useful in the treatment and the protection of UV radiation-induced damage. Moreover, ascorbyl palmitate is a known vitamin C (an ester of ascorbic acid). Therefore, one of ordinary skill in the art would have reasonably expected that combining vitamin D3 and ascorbyl palmitate known useful for the same purpose, i.e., treating radiation damage, in a composition to be would improve the therapeutic effect in treating radiation injury.

Further, both flavonoid / flavonoid derivatives and ginseng are known antioxidants and also known to be useful in the protection of radiation injury. Therefore, one of ordinary skill in the art would have reasonably expected that further adding both flavonoid / flavonoid derivatives and ginseng to the composition herein known useful for

the same purpose, in a composition to be administered would provide additive effects for the therapeutic treatment in radiation injury.

Furthermore, one of ordinary skill in the art would have reasonably expected that the combination herein would have same or substantially same beneficial therapeutic effects in proton, fluoroscopic, alpha, beta, or gamma radiation, as in UV radiation-induced damage.

Since all active composition components herein are known to useful to treat radiation injury, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 5 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett (US 6,051,602, PTO-892), and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record), further in view of Ishida et al. (US 5141741, of record) or Nguyen et al. (US 5650137, of record).

The same disclosures of KITA, K, and Bissett et al. and Darr et al. in view of Shimoi et al. and Kim et al. have been discussed in the 103(a) rejection set forth above.

The prior art does not expressly disclose the employment of the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition

to be administered in a method for the treatment or reduction of radiation injury. Ishida et al. discloses that alpha-lipoic acid and vitamin A, B, C, D, E, F, K, P, U are known to be useful in the protection of UV radiation or anti-sunburn in human skin. See abstract, col.5 lines 65-68.

Nguyen et al. discloses that superoxide dismutase or the porphyrins such as chlorophyllin, alone or in combination are antioxidants and have protective effects to human skin including against UV radiation. See abstract, col. 1, col. 2, lines 20-31, col.3 lines 40-66, claims 1-11.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition to be administered in a method for the treatment or reduction of radiation injury.

One having ordinary skill in the ad at the time the invention was made would have been motivated to employ the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition to be administered in a method for the treatment or reduction of radiation injury, since alpha-lipoic acid or chlorophyllin or superoxide dismutase, alone or their combination is well known to be useful for the protection and treatment of the skin and scalp from harmful UV radiation, as those known antioxidants taught by the cited prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that alpha-lipoic acid or chlorophyllin or superoxide dismutase, alone or their combination would have the same usefulness and provide additive effects for the therapeutic

treatment in radiation injury. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Response to Arguments

Applicant argues that Kita et al. does not teach the use of vitamin D compounds as blocking agents against any type of ionization radiation, even if such ionization radiation were UV radiation having a wavelength of 40-124 nm. This is not persuasive because the wavelength range (40-124 nm) limitation is not found in the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wavelength range of 40-124 nm) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, the claim language "comprising" is open-ended or inclusive, which does not exclude UV radiation. The Examiner interprets the claims as a method for the reduction or treatment of radiation injury, for example proton, fluoroscopic, alpha, beta, and gamma radiation, atmospheric radiation, or UV radiation.

Applicant argues Kita et al. teach the topical use of vitamin D compounds and not oral administration. This is found not persuasive because Kita clearly teach that therapeutic vitamin D can be orally administered (col. 1, lines 42-44). Whether or not Kita meant for this oral administration to be applicable for treating radiation injury or other diseases is immaterial, as long as oral administration is disclosed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER